K130664

510(k) Summary
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18-Jun-13

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Sequim, WA 98382

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Official Contact: David Green, Product Manager

Proprietary or Trade Name: HydroMax™ HMEF

Common/Usual Name: Bacterial / Viral Filter

Classification Name: Filter, Bacterial, Breathing Circuit,
CAH – 21 CFR 868.5260
Class 2

Predicate Devices: GE (Engstrom) HMEF 1000 – K964204

Device Description
The HydroMax™ HMEF is standard configuration housing with a CO_2 sampling port.

The common features are:
- All have standard conical 15 mm / 22 mm fittings for connections
- Female luer lock port for gas sampling for end-tidal CO_2

The principle of operation:
- The filter media is an electrostatic type of media and filters via electrostatic attraction
- The HME media a porous foam that has hygroscopic properties to retain and release moisture from the patient

Indications for Use
For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is desired and to add and retain moisture in the circuit as required.

It is single patient use, disposable for patients with Tidal Volumes > 250 ml.

Duration of use < 24 hours.

Environment of Use
Hospital, sub-acute care, and home settings

Predicate Device Comparison:

The proposed HydroMAX™ HMEF is similar in all respects to the predicate device, GE (Engstrom) HMEF 1000 – K964204.

Comparative **Table 5.1** discusses the major features of the proposed device and the legally marketed predicate device.

The HydroMAX™ HMEF is viewed as substantially equivalent to the predicate device based upon the following:

Indications –

- Intended to be placed in circuit for filtration and humidification of inspired and expired gases – GE (Engstrom) HMEF 1000 – K964204.

Discussion – The indications for use are identical for the proposed and predicate device.

Technology –

- The filter and HME media are standard materials and the fundamental principle of operation are identical to the predicate.

Discussion - There are no differences in technology between the HydroMAX™ HMEF and the predicate GE (Engstrom) HMEF 1000 – K964204

Environment of Use –

- Home, Hospitals, Sub-acute institutions

Discussion - The environment of use are identical between the HydroMAX™ HMEF and the predicate GE (Engstrom) HMEF 1000 – K964204

Table 1 – Comparison to the Predicate

Features	Predicate GE (Engstrom) HMEF 1000 K964204	Proposed HydroMAX™ HMEF
Indications for use	For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is required.	For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is required.
Patient Use / Duration if use	Single patient use, disposable, < 24 hours	Single patient use, disposable, < 24 hours
Environment of Use	Hospital, Sub-acute Institutions, Home	Hospital, Sub-acute Institutions, Home
Patient Population	Tidal volume > 300 ml	Tidal volume > 250 ml
Contraindications	None	None
Standard 22 / 15 mm connections Per ISO 5356-1	Yes	Yes
Luer port for gas sampling Per ISO 594-2	Yes	Yes
Various configurations	Straight, angled	Straight
Filtration method	Electrostatic	Electrostatic
Placement within the circuit	Patient -side	Patient –side
Weight (gm)	24 gm	21 gm
Internal volume/ Dead space per ISO 9360-1	77ml	56 ml
Bacterial / Viral filtration efficiency (Nelson Labs)	BFE – 99.9999% VFE – 99.99%	BFE - >99.99969% VFE - >99.9946%
Moisture Output (mg/L)	Vt 250 – N/A Vt 500 – 33 Vt 750 – 32 Vt 1000 – 30	Vt 250 – 36.5 Vt 500 – 35.13 Vt 750 – 33.2 Vt 1000 – 32.53.
Moisture Loss (mg/L)	Vt 250 – N/A Vt 500 – 4.5 Vt 750 – 5.5 Vt 1000 – 7.5	Vt 250 – 7.63 Vt 500 – 8.97 Vt 750 – 10.9 Vt 1000 – 11.57

Features	Predicate GE (Engstrom) HMEF 1000 K964204	Proposed HydroMAX™ HME/F
Pressure Drop	1.0 cmH_2O @ 30 lpm 2.3 cmH_2O @ 60 lpm N/A	0.7 cmH_2O @ 30 lpm 2.0 cmH_2O @ 60 lpm 3.5 cmH_2O @ 90 lpm
Filter integrity per ASTM F316-80	N/A	244.43 microns
Housing burst strength	N/A	>10 psi < 20 psi
Leakage per ISO 9360-1 6.4	N/A	0 ml/min @ 70 cm H_2O
Compliance per ISO 9360-1 6.5	N/A	1.1 ml/kPa
Materials	Standard materials to ISO 10993-1	Standard materials to ISO 10993-1
Standards	ISO 9360-1 HME	ISO 9360-1 HME

Non-clinical Testing Summary -

Performance – Bench Testing
We performed a number of bench tests pre- and post-conditioning these included the results are summarized in **Table 2** below.

- Filtration efficiency
  - Bacterial / Viral filtration efficiency per Nelson Laboratories
  - Pre – and Post – conditioning performance
  - Includes Pressure Drop per ISO 9360-1
  - Dead space per ISO 9360-1
- Leakage test per ISO 9360-1
- Filter integrity per ASTM F316-80
- Housing burst strength
- Environmental and Mechanical Testing

Table 2 – Summary of Non-clinical Testing

Performance Characteristics	Results
Pressure Drop (cmH_2O)	0.7 cmH_2O @ 30 lpm 2.0 cmH_2O @ 60 lpm 3.5 cmH_2O @ 90 lpm
Filter Integrity (Bubble Point) Test	244.43 microns
Dead Space (Internal Compressible Volume in ml)	56 ml
Leakage per ISO 9360-1 6.4	0 ml/min @ 70 cm H_2O
Compliance per ISO 9360-1 6.5	1 ml/kPa
Housing Burst Pressure (psig)	>10 psi < 20 psi
Mechanical Vibration and Shock	Pressure Drop 2.0 cm H_2O @ 60 lpm
Storage - High and Low Temperature and Humidity	Pressure Drop 2.0 cm H_2O @ 60 lpm
Bacterial Filtration Efficiency (BFE) %	>99.99969% @ 30 lpm
Viral Filtration Efficiency (VFE) %	>99.9946% @ 30 lpm

Material – Biocompatibility

- The materials are identical to predicates that have the identical intended use.
- This device would be considered –
    - External communicating / Tissue / mucosal / limited duration (< 24 hr)
    - However based on the potential of accumulative exposure the device would be consider permanent duration contact.

Discussion: We are utilizing identical materials and provide Material Certifications.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

A-M Systems, Inc.
c/o Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K130664
Trade/Device Name: HydroMax™ HMEF
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing circuit bacterial filter
Regulatory Class: II
Product Code: CAH
Dated: May 14, 2013
Received: May 15, 2013

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Kwame Ulmer, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number; K130664

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use__** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James J. Lee Digitally signed by James J. Lee DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=James J. Lee, 0.9.2342.19200300.100.1.1=2000954859 Date: 2013.06.19 13:58:46 -04'00'

Acting BC for Dr. Anya Harry

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130664